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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,776	06/18/2007	Masato Miyake	690121.408USPC	2445

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,776	MIYAKE ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-5,8,9,11-18 and 20-54* is/are pending in the application.

5a) Of the above claim(s) *3,5,9 and 24-54* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,4,8,11-18 and 20-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 11, 2010 has been entered.

Claims 1, 3-5, 8, 9, 11-18, 20-54 are pending. Claims 3, 5, 9, 24-54 remain withdrawn. The species of CD49e integrin is rejoined for examination. Claims 1, 4, 8, 11-18, 20-23 are currently being examined as drawn to the elected species of integrin receptor CD29 and rejoined CD49e.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4, 8, 11, 12, 15-17, 22, and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Volpers et al (J of Virology, February 2003, 77:2093-2104), as evidenced by GIBCO product insert for OPTI-MEM® (Form No. 2017, June 2001, one page).

Volpers et al teach a composition comprising: a monoclonal antibody that binds to α_7 integrin receptor and an adenoviral vector DNA for enhanced, targeted gene transfer into cells expressing α_7 integrin receptor, wherein the cells are cancer cells, skeletal muscle cells, wherein the cells are *in vitro* on a solid support, wherein the composition comprises OPTI-MEM® (p. 2094, col. 1; p. 2095, col. 1-2; p. 2098, col. 2 to p. 2099, col. 1). The α_7 integrin binds laminin.

As evidenced by the GIBCO product insert for OPTI-MEM®, this media comprises salt sodium bicarbonate (see Formulation, col. 1).

3. Claims 1, 4, 8, 11-17, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wickham et al (J of Virology, 1996, 70:6831-6838), as evidenced by Sigma-Aldrich, Dulbecco's Modified Eagle's Medium, Product description, revised April 2007.

Wickham et al teach a composition comprising: a monoclonal antibody that binds α_v integrin receptor (CD49e) and an adenoviral DNA vector used to enhance gene transfer into cells expressing α_v integrin; wherein the cells are carcinoma cells, human

intestinal smooth muscle cells, and aortic smooth muscle cells; wherein the cells were *in* vitro on solid support; wherein the composition comprises DMEM (Dulbecco's Modified Eagle's Medium) (abstract; p. 6832, col. 1-2; Figure 2). Integrin α_v binds fibronectin.

As evidenced by Sigma-Aldrich, DMEM comprises salt, sodium chloride.

4. Claims 1, 4, 8, 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2006/0127398 A1, Lundgren-Akerlund, claiming priority to April 16, 2003.

Lundgren-Akerlund teach a composition comprising a monoclonal antibody that binds integrin receptor $\alpha_{10}\beta_1$ (ITGA10/CD29) linked to genetic material for enhanced gene transfer into cells expressing the integrin; wherein the cells are mesenchymal stem cells (MSCs) and any cell that express $\alpha_{10}\beta_1$ including cartilage, bone, tendon, ligament and muscle; wherein the antibody is used to deliver naked DNA or DNA/cationic liposome/polycation complexes to $\alpha_{10}\beta_1$ expressing cells; wherein gene transfer can occur *in vivo* for gene therapy or *in vitro* for cells in culture, each of which includes cells in liquid or solid phase; wherein $\alpha_{10}\beta_1$ interacts with collagen (abstract; Figure 4; [19-21]; [58]; [70-71]; [81]; [346- 367]; claims 36 and 37).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2006/0127398 A1, Lundgren-Akerlund, claiming priority to April 16, 2003 **or** Wickham et al (J of Virology, 1996, 70:6831-6838) **or** Volpers et al (J of Virology, February 2003, 77:2093-2104), each in view of Khurana et al (J of Cerebral Blood Flow and Metabolism, 2000, 20:1360-1371), El Ouahabi et al (J Histochemistry & Cytochemistry, 1999, 47:1159-1166), and Wolff et al (J Cell Science, 1992, 103:1249-1259).

Lundgren-Akerlund teaches a composition comprising a monoclonal antibody that binds integrin receptor $\alpha_{10}\beta_1$ (ITGA10/CD29) linked to genetic material for enhanced gene transfer into cells expressing the integrin; wherein the cells are mesenchymal stem cells (MSCs) and any cell that express $\alpha_{10}\beta_1$ including cartilage, bone, tendon, ligament and muscle. Lundgren-Akerlund teaches that the antibody is used in conjunction with naked DNA or DNA/cationic liposome/polycation complexes, and viral vectors, such as adenovirus, to target gene transfer to $\alpha_{10}\beta_1$ expressing cells. Lundgren-Akerlund teach the gene transfer can occur *in vivo* for gene therapy or *in vitro* for cells in culture, as set forth above.

Wickham et al teach a composition comprising: a monoclonal antibody that binds α_v integrin receptor (CD49e) and an adenoviral DNA vector used to enhance gene transfer into cells expressing α_v integrin; wherein the cells are carcinoma cells, human intestinal smooth muscle cells, and aortic smooth muscle cells; wherein the cells were *in vitro*, as set forth above.

Volpers et al teach a composition comprising: a monoclonal antibody that binds to α_7 integrin receptor and an adenoviral vector DNA for enhanced, targeted gene transfer into cells expressing α_7 integrin receptor, wherein the cells are cancer cells or skeletal muscle cells, wherein the cells are *in vitro*, as set forth above.

Lundgren-Akerlund, Wickham et al, and Volpers et al do not teach that the composition further comprises a gold colloidal particle.

Khurana et al teach using gold colloidal particles in combination with adenovirus-mediated gene transfer into arterial cells in order to visualize successful gene transfer and expression in the cells by electron microscopy (p. 1361, col. 2; p. 1363, col. 2 to p. 1364; p. 1365, col. 2; Figure 3).

El Ouahabi et al teach using gold colloidal particles in combination with cationic liposome gene transfer into cell culture in order to visualize successful gene transfer in the cells by electron microscopy (p. 1161; Figure 2).

Wolff et al teach using gold colloidal particles in combination with plasmid DNA gene transfer into muscle cells in order to visualize successful gene transfer in the cells by electron microscopy (p. 1250, col. 2; Figures 11-13).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to and one would have been motivated to add colloidal gold to the composition taught by Lundgren-Akerlund, Wickham et al, and Volpers et al for purposes of studying and visualizing successful gene transfer as taught by Khurana et al, El Ouahabi et al, and El Ouahabi et al. One of ordinary skill in the art would have a reasonable expectation of success adding colloidal gold to the composition of

Lundgren-Akerlund, Wickham et al, and Volpers et al because Khurana et al, El Ouahabi et al, and El Ouahabi et al teach combinations of gold colloidal particles and various gene transfer compositions for visualization of gene transfer is known and successfully accomplished.

6. All other rejections recited in the Office Action mailed November 10, 2009 are hereby withdrawn in view of amendments and arguments.

7. **Conclusion:** No claim is allowed. Applicants' arguments are not directed to the new rejections above.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LAURA B GODDARD/
Primary Examiner, Art Unit 1642